

REMARKS

Applicants thank the Examiner for the courtesy of a telephonic interview held on January 3, 2005. Compliant with M.P.E.P § 713.04, Applicants provide a separate summary in Section II below. Entry of the claim amendments and consideration of the following remarks, which address the rejections set forth in the Office Action dated September 1, 2004, is respectfully requested.

A separate petition for a 1-month extension of time accompanies this amendment.

I. Amendments

The preamble of claim 18 is amended to recite "A method of decreasing the alanine aminotransferase (ALT) blood level in a human subject". Basis for the amendment is found in Figs. 3-7 and in Tables 8 and 10, and on page 10, line 16. Claim 18 is also amended to recite a dosage of 2×10^3 U/day, as set forth on page 5, line 1.

Claim 22 is amended for consistency with the changes to claim 18, and recites a dosage of greater than 4×10^8 Units per day, as set forth on page 5, line 2.

Claims 24, 25, and 26 are amended to consistency with the changes to claim 18.

II. Summary of Interview

A telephonic interview with the Examiner and Applicant's representative Judy Mohr was held on January 3, 2005. During the interview, the rejections set forth in the Final Office action dated September 1, 2004 were discussed. Specifically, and with respect to the rejection under 35 U.S.C. § 112, first paragraph, possible amendments to the preamble and the possibility of presentation of additional supporting data were discussed. With respect to the rejection under 35 U.S.C. § 103, amending the claim to fall outside the dosage range disclosed in the prior art was discussed.

III. Obvious-type double patenting rejection

Claim 21 remains provisionally rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over claim 8 of co-pending Application No. 10/698,927.

Applicants had previously asked this rejection be held in abeyance. Applicants note that application serial no. 10/698,927 is abandoned, and a copy of the Notice of Abandonment is attached herewith. Thus, withdrawal of the double-patenting rejection based on 10/698,927 is respectfully requested.

Applicants draw to the Attention of the Examiner presently pending application no. 10/719,472, which is a continuation-in-part of 10/698,927. In light of the amendments to the presently pending claims, it is believed that no double-patenting issues arise.

IV. Rejection under 35 U.S.C. §112, first paragraph

Claims 18-26 were rejected under 35 U.S.C. §112, first paragraph as allegedly failing to comply with the enablement requirement. Specifically, the Examiner finds that "...the human clinical trial data presented in the specification do not show any clear pattern relating increased OAS to improvement in the subject's condition," (Office Action mailed March 19, 2004; paragraph bridging pages 3 and 4). Applicants respectfully traverse this rejection for the following reasons.

The presently pending claims as amended are directed to a method for decreasing the blood alanine aminotransferase (ALT) level in a human subject by orally administering interferon-tau. The effectiveness of orally-administered interferon-tau for decreasing ALT levels is illustrated in the data presented in Figs. 3-7 and Tables 8 and 10.

In light of the claim amendments, withdrawal of the rejection under 35 U.S.C. §112, first paragraph is respectfully requested.

V. Rejection Under 35 U.S.C. § 103

Claims 4-10 were rejected under 35 U.S.C. §103 as allegedly obvious in view of Soos *et al.* (U.S. Patent No. 6,372,206). This rejection is respectfully traversed for the following reason.

Summaries of the present invention and of the cited Soos *et al.* document are provided in Applicants' response submitted June 21, 2004.

A. Analysis

According to the M.P.E.P. § 2143.03, "to establish a prima facie case of obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. All words in a claim must be considered in judging the patentability of that claim against the prior art." [citations omitted].

The pending method claims require oral administration of IFN τ to a human at a daily dosage of between 2×10^8 and 10^{10} Units.

Soos *et al.* nowhere show or suggest oral administration of interferon-tau at a daily dose between $2 \times 10^8 - 10^{10}$ Units. The highest dose disclosed by Soos *et al.* is 1×10^8 units per day (Col. 4, line 34). Nothing in Soos *et al.* guides one to select a dose higher than that disclosed in Soos *et al.*

Accordingly, since the cited art does not teach or suggest all of the features of the present claims, Soos *et al.* cannot be said to render the claimed invention obvious. Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §103(a).

VI. Conclusion

In view of the above amendments and remarks, the applicants submit that the claims now pending are in condition for allowance. A Notice of Allowance is, therefore, respectfully requested.

If in the opinion of the Examiner a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 838-4402.

Respectfully submitted,

Date: 1/3/05

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
10/698,927	10/31/2003	Yoshihiro Sokawa	55600-8013.US00

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CONFIRMATION NO. 6141
ABANDONMENT/TERMINATION
LETTER

OC000000014794961

OC000000014794961

Date Mailed: 12/20/2004

NOTICE OF ABANDONMENT UNDER 37 CFR 1.53 (f) OR (g)

The above-identified application is abandoned for failure to timely or properly reply to the Notice to File Missing Parts (Notice) mailed on 03/17/2004.

- The retention fee of \$130 was received.

A petition to the Commissioner under 37 CFR 1.137 may be filed requesting that the application be revived.

Under 37 CFR 1.137(a), a petition requesting the application be revived on the grounds of **UNAVOIDABLE DELAY** must be filed promptly after the applicant becomes aware of the abandonment and such petition must be accompanied by: (1) an adequate showing of the cause of unavoidable delay; (2) the required reply to the above-identified Notice; (3) the petition fee set forth in 37 CFR 1.17(l); and (4) a terminal disclaimer if required by 37 CFR 1.137(d).

Under 37 CFR 1.137(b), a petition requesting the application be revived on the grounds of **UNINTENTIONAL DELAY** must be filed promptly after applicant becomes aware of the abandonment and such petition must be accompanied by: (1) a statement that the entire delay was unintentional; (2) the required reply to the above-identified Notice; (3) the petition fee set forth in 37 CFR 1.17(m); and (4) a terminal disclaimer if required by 37 CFR 1.137(d).

Any questions concerning petitions to revive should be directed to the "Office of Petitions" at (703) 305-9282. Petitions should be mailed to: Mail Stop Petitions, Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450.

*A copy of this notice **MUST** be returned with the reply.*

Olivia Adams - Lyle
 Customer Service Center
 Initial Patent Examination Division (703) 308-1202

PART 2 - COPY TO BE RETURNED WITH RESPONSE